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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,449	03/24/2004	Karin Jooss	3802-090-27 CIP	3354

29585 7590 02/23/2007  
DLA PIPER US LLP  
153 TOWNSEND STREET  
SUITE 800  
SAN FRANCISCO, CA 94107-1957

EXAMINER
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OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/23/2007	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/807,449

Applicant(s)

JOOSS ET AL.

Examiner

ILIA OUSPENSKI

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1644

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-43 is/are pending in the application.
- 4a) Of the above claim(s) 12 - 18, 21 - 22, 25, and 27 - 43 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1 - 11, 19 - 20, 23 - 24, and 26 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                     | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

## DETAILED ACTION

1. Applicant's amendment/response, filed on 11/21/2006, is acknowledged.

2. Applicant's Remarks state on page 8, first paragraph, that claims 1 and 28 have been cancelled, while these claims are listed as pending in the listing of claims filed on 11/21/2006. Applicant is invited to clarify the status of these claims. For examination purposes, claims 1 and 28 are presently treated as pending.

Further, claims 20, 23, 24, and 26 are listed as "withdrawn," while they appear to read on the elected invention. Applicant is invited to clarify the status of these claims. For examination purposes, claims 20, 23, 24, and 26 presently remain under consideration.

3. Applicant's election with traverse of a single Invention (which reads on a method for cancer therapy, comprising administering a cytokine-expressing cellular vaccine and an anti-OX40 antibody) in the reply filed on 11/21/2006 is acknowledged.

Claims 1 – 11, 19 – 20, 23 – 24, and 26 read on the elected Invention.

The traversal is on the grounds that the generic claim exemplified in claim 1 is allegedly allowable.

This is not found persuasive, because, as set forth in the Restriction Requirement mailed on 10/24/2006, the methods employing the various recited therapeutic agents differ with respect to ingredients, which are patentably distinct

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because their structures, physicochemical properties and/or mode of action are different, and they do not share a common structure that is disclosed to be essential for common utility. Furthermore, they require non-coextensive searches in the scientific literature. Therefore, each method is patentably distinct, and searching of these Inventions would impose an undue burden.

The requirement is still deemed proper and is therefore made FINAL.

4. Claims 12 – 18, 21 – 22, 25, and 27 – 43 are withdrawn from further consideration by the Examiner, under 37 C.F.R. § 1.142(b), as being drawn to nonelected inventions.

***Claims 1 – 11, 19 – 20, 23 – 24, and 26 are under consideration in the instant application, as they read on the elected invention of a method for cancer therapy, comprising administering a cytokine-expressing cellular vaccine and an anti-OX40 antibody.***

5. Upon further consideration, it is determined that election of Species of the claimed Invention is required under 35 USC 121:

#### ***Species Election***

6. This application contains claims directed to the following patentably distinct Species of the claimed Invention, wherein the cells of the cytokine-expressing cellular vaccine are:

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- A. autologous;
- B. allogenic; or
- C. bystander.

These species are distinct because the methods differ with respect to ingredients, which ingredients differ with respect to their physicochemical properties and mode of action. Additionally, the examination of these species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable.

7. This application contains claims directed to the following patentably distinct Species of the claimed Invention, wherein the cancer is:

- A. prostate cancer;
- B. non-small cell lung carcinoma; or
- C. pancreatic cancer.

These species are distinct because the pathological conditions differ in etiologies and therapeutic endpoints; thus each condition represents patentably distinct subject matter. Furthermore, the examination of species would require different searches in the scientific literature. As such, it would be burdensome to search these Species together.

Applicant is required under 35 USC 121 to elect a single disclosed species to which the claims would be restricted if no generic claim is finally held to be allowable.

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8. Applicant is advised that a response to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 C.F.R. § 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. M.P.E.P. § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. § 103 of the other invention.

9. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

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10. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

A handwritten signature in cursive script, reading "Ilia Ouspenski".

ILIA OUSPENSKI, Ph.D.

Patent Examiner

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February 16, 2007